

## REMARKS/ARGUMENTS

The present Amendment is responsive to the final Office Action mailed November 5, 2008, in the above-identified application.

Claims 1, 2, 4, 7, 9-11, 15, 19 and 20 were pending in the Application prior to the present Amendment.

Applicants amend Claim 1 to clarify features recited therein, add new Claim 21 and respectfully request a reconsideration of the rejection.

Applicants thank the Examiner for the courtesy extended during the telephone interview of June 22, 2009.

### *Rejection of Claim 1 under 35 U.S.C. § 112*

Claim 1 was rejected under 35 U.S.C. 112, second paragraph, because the Examiner believes that two recited functions of the pressure regulator are substantially the same. Applicants amended Claim 1 to more particularly recite that the pressure regulator is “configured to continuously self-regulate a pressure of the gas supplied from the source of gas to continuously maintain the pressure of the supplied gas at a constant and predetermined level and so as to continuously maintain the pressure applied to the exterior walls of the bag at the constant and predetermined level throughout a duration of dispensing of the liquid.” Applicants respectfully submit that Claim 1 is now in compliance with 35 U.S.C. 112, second paragraph. Withdrawal of the rejection is respectfully requested.

### *Rejection of Claims 1, 2, 4, 7, 9-11, 15, 19 and 20 under 35 U.S.C. § 103*

Claims 1, 2, 4, 7, 9-11, 15, 19 and 20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Laing (CA 2,083,555) in view of Keime (GB 2,165,312). Reconsideration of this rejection is respectfully requested.

As discussed during the interview, provided with this response is a Declaration of Paul Dastoor under 37 C.F.R. §1.132 (“Dastoor Declaration”) filed in support of the patentability of the present invention. Dastoor Declaration provides evidence that the claimed apparatus yields results unexpected to one of ordinary skill in the art at the time of the invention. It is submitted

to traverse the Examiner's finding(s) that pending claims are "obvious" to one having ordinary skill in this art pursuant to 35 USC §103.

Claim 1 recites a pressure regulator positioned between the source of gas and the flexible bag. As recited in Claim 1, and disclosed in the original specification (see, page 6, lines 16-19), the pressure regulator self-regulates the pressure of the gas supplied from the source of gas such that this pressure of the supplied gas is maintained at a constant and predetermined level throughout the duration of dispensing the liquid. In other words, the pressure regulator itself (i.e., without using any additional mechanism) maintains the constant and predetermined pressure of the supplied gas throughout dispensation of the liquid. Further, as a result of maintaining the pressure of the supplied gas at the constant and predetermined level, the flow rate of the liquid from the flexible bag is continuously constant because the pressure applied to the exterior walls of the flexible bag is also maintained at the constant and predetermined level. As evidenced by the Dastoor Declaration, this advantage is not realized by the cited references and cannot be achieved by the devices disclosed therein.

Laing discloses a flexible bag 40 located inside a rigid housing 20 and a pressure pump 58 connected to an air bag 30 inside the housing 20 through a line 35. As air is supplied to the air bag inside the housing, the air bag expands and applies pressure to the flexible bag 40 causing it to dispense fluid. As the fluid is dispensed from the bag 40 through an outlet line 45, the pressure of the dispensed fluid is monitored using an isolation device 60 connected to both the outlet line 45 and the pump 58. Laing teaches that when the fluid pressure in the outlet line 45 falls below a set level, isolation device 60 communicates with the pump 58 causing the pump to pump more air, thus, increasing the air pressure inside the air bag 30 and increasing the pressure on the flexible bag 40. See, Laing, page 12, line 25 - page 13, line 9 (emphasis added). Therefore, in Laing, the pressure of the air supplied from the pump is not continuously maintained at the constant and predetermined level, as required by Claim 1, and the pressure applied to the flexible bag is not continuously maintained at the constant and predetermined level, as also required by Claim 1. Further, as discussed during the interview and shown in the enclosed Dastoor Declaration, as a result of the pressure fluctuations in the device disclosed in Laing, such device cannot achieve the accuracy results achieved by the device constructed in

accordance with Claim 1 and cannot be utilized in medical applications requiring high degree of precision (for which the device of the present Application is designed).

As further discussed during the interview, Keime cannot remedy the above deficiency of Laing because Keime discloses a portable device for use in a rapid infusion delivery environment, i.e., where a constant delivery rate is not clinically required. See, Keime, page 1, lines 7-10. Specifically, Keime discloses a manually operable pressure injector in which, after a needle is introduced into a patient, the operator changes the pressure applied to the flexible bag 2 by manually operating the flow regulator 23 adjusting the flow of gas into the casing 1 containing the flexible bag (Keime, page 2, lines 76-85). The operator continually consults the pressure gauge 17 on the face of casing 1, which indicates the pressure in the inner space of the casing and adjusts the pressure during dispensation of the fluid using the flow regulator 23 (Keime, page 2, lines 20-22 and 81-90). Thus, the Keime device constantly overshoots a predetermined pressure threshold and then allows the operator to manually adjust the pressure. Therefore, the pressure and the flow-rate of the liquid fluctuate throughout the delivery process. See, Dastoor Declaration, par. 18.

Accordingly, Keime does not disclose or suggest a pressure regulator continuously maintaining the pressure of the supplied gas at the constant and predetermined level throughout dispensation of the fluid or a pressure regulator continuously maintaining the pressure applied to the flexible bag at the constant and predetermined level throughout dispensation of the fluid, as required by Claim 1.

Accordingly, even taken together in combination, Keime and Laing do not disclose or suggest the recitations of Claim 1.

Claims 2, 4, 7, 9-11, 15, 19 and 20 depend from Claim 1. Therefore, claims 2, 4, 7, 9-11, 15, 19 and 20 are allowable over the cited prior art at least for the same reasons as claim 1 and, further, on their own merits.

Applicants appreciate the Examiner's suggestion to include further limitations as to the structure of the pressure regulator recited in the present claims. Applicants added new Claim 21

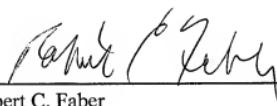
reciting that the pressure regulator is a compression spring controlled piston device which includes a needle valve regulating the pressure of the supplied gas. Support for the new Claim 21 is found on page 6, lines 5-6, of the original specification. Limitations of the new Claim 21 are not disclosed or even suggested by the cited prior art references. Accordingly, Applicants respectfully submit that Claim 21 is allowable over the prior art of record.

In view of the foregoing discussion, withdrawal of the rejections and allowance of the application are respectfully requested.

Respectfully submitted,

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